



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0153]

Guidance for Industry and Food and Drug Administration Staff; Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act.” This guidance document establishes the procedures for the submission, FDA review, and FDA response to requests for information regarding the class in which a device has been classified.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and

Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8419. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Bob Gatling,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 1640,

Silver Spring, MD 20993-0002,

301-796-6560;

or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining FDA's views about the classification and the regulatory requirements that may be applicable to a particular device. This guidance describes procedures for the submission, FDA review, and FDA response to requests for information with respect to the classification of a device or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) requests for information. FDA's response to section 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

In the Federal Register of April 29, 2010 (75 FR 22599), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by July 28, 2010. No comments were received. The guidance announced in this notice finalizes the draft guidance of the same title.

Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), requires FDA to collect user fees for section 513(g) requests for information. Elsewhere in this issue of the Federal Register, FDA is publishing a document announcing the availability of a guidance entitled "Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information."

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on procedures

regarding section 513(g) requests. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive “Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act,” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8419 to receive a hard copy. Please use the document number 1671 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0705.

This guidance also refers to currently approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 have

been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR 860.123 have been approved under OMB control number 0910-0138.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2012.

Nancy K. Stade,

Deputy Director for Policy,

Center for Devices and Radiological Health.

[FR Doc. 2012-8226 Filed 04/05/2012 at 8:45 am; Publication Date: 04/06/2012]